

Notice of Allowability	Application No.	Applicant(s)	
	10/004,522	HANNA ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06 September 2005.
2. ☒ The allowed claim(s) is/are 20-39 and 41-80.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John-Paul Cherry on 12 December 2005.

The application has been amended as follows:

In the second line of Claim 20, the phrase

“the other, but which has a finite gradient in a relative additive concentration, which concentration increases radially outwards, which particulate coformulation comprises either spherical”

has been deleted and has been replaced with the phrase

“the other formed from a co-precipitation process containing a supercritical fluid, wherein each particle contains a particle core having a first concentration by weight of the active substance within a range from about 90% to about 100%, a particle surface having a second concentration by weight of the active substance within a range from about 0% to about 5%, a relative additive concentration increasing radially outwards along a finite gradient and the particles are spherical”.

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In Claim 20, the phrase “or of needle-like particles” has been deleted and has been replaced with the phrase “or needle-like particles”.

In Claim 20, the phrase “or of plate-like particles” has been deleted and has been replaced with the phrase “or plate-like particles”.

In Claim 21, the phrase
“particles have an additive-rich surface region without a distinct boundary.”
has been deleted and has been replaced with the phrase
“particle surface is an additive-rich surface without a distinct boundary between the
particle core and the particle surface.”

In second line of Claim 24, the phrase “wherein the” has been deleted and has been replaced with the phrase “wherein an”.

At the end of Claim 28, the phrase “masking the flavour or odour of” has been deleted and has been replaced with the phrase “a flavor or odor of”.

In Claim 29, the phrase “taste or odour masking agent.” has been deleted and has been replaced with the phrase “taste masking agent or an odor masking agent.”

In Claim 36, the phrase

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“wherein the spherical or approximately spherical particles have a volume mean diameter above about”

has been deleted and has been replaced with the phrase

“wherein the particles are the spherical or approximately spherical particles having a volume mean diameter of at least about”

In Claim 43, the phrase “wherein the spherical particles have a” has been deleted and has been replaced with the phrase “wherein the particles are the spherical particles having a”.

In Claim 44, the phrase “wherein the spherical particles have a” has been deleted and has been replaced with the phrase “wherein the particles are the spherical particles having a”.

In Claim 45, the phrase “wherein the spherical particles have a” has been deleted and has been replaced with the phrase “wherein the particles are the spherical particles having a”.

In the first and second lines of Claim 46, the phrase “and the spherical particles have a” has been deleted and has been replaced with the phrase “and the particles are the spherical particles having a”.

In Claim 47, the phrase “wherein the spherical particles have a” has been deleted and has been replaced with the phrase “wherein the particles are the spherical particles having a”.

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In the first and second lines of Claim 48, the phrase “and the spherical particles have a” has been deleted and has been replaced with the phrase “and the particles are the spherical particles having a”.

In Claim 49, the phrase
“within particulate; and
an additive concentration having a finite gradient increasing radially from a center towards an outer surface of the particulate, wherein the particulate contains spherical”
has been deleted and has been replaced with the phrase
“within particulate formed from a co-precipitation process containing a supercritical fluid, wherein each particle contains a particle core having a first concentration by weight of the active substance within a range from about 90% to about 100%, a particle surface having a second concentration by weight of the active substance within a range from about 0% to about 5%, an additive concentration having a finite gradient increasing radially from a center towards the particle surface and the particles are spherical”.

In Claim 50, the phrase
“within particulate; and
an taste masking concentration having a finite gradient increasing radially from a center towards an outer surface of the particulate, wherein the particulate contains spherical”
has been deleted and has been replaced with the phrase

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“within particulate formed from a co-precipitation process containing a supercritical fluid, wherein each particle contains a particle core having a first concentration by weight of the active substance within a range from about 90% to about 100%, a particle surface having a second concentration by weight of the active substance within a range from about 0% to about 5%, a taste masking agent concentration having a finite gradient increasing radially from a center towards the particle surface and the particles are spherical”.

In Claim 51, the phrase

“a surface of each particle within the particulate.”

has been deleted and has been replaced with the phrase

“a particle surface of each particle within the particulate, wherein each particle contains a particle core having a first concentration by weight of the active substance within a range from about 90% to about 100% and the particle surface having a second concentration by weight of the active substance within a range from about 0% to about 5%.”

In the first and second lines of Claim 52, the phrase

“the surface contains an additive-rich surface region without a distinct physical boundary between a particle core and the surface.”

has been deleted and has been replaced with the phrase

“the particle surface is an additive-rich surface without a distinct physical boundary between the particle core and the particle surface.”

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In the second line of Claim 54, the phrase “the surface” has been deleted and has been replaced with the phrase “the particle surface”.

In the second line of Claim 55, the phrase “or odor” has been deleted and has been replaced with the phrase “or an odor”.

In Claim 56, the phrase “the surface” has been deleted and has been replaced with the phrase “the particle surface”.

In the second line of Claim 62, the phrase “or odour” has been deleted and has been replaced with the phrase “or an odor”.

In Claim 69, the phrase “the particulate contains” has been deleted and has been replaced with the phrase “the particles are”.

In Claim 70, the phrase “the particulate contains” has been deleted and has been replaced with the phrase “the particles are”.

In Claim 71, the phrase “the particulate contains” has been deleted and has been replaced with the phrase “the particles are”.

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In Claim 73, the word “according” has been deleted and has been replaced with the word “of”.

In the second line of Claim 78, the phrase “the particulate contains” has been deleted and has been replaced with the phrase “the particles are”.

In the second line of Claim 80, the phrase “the particulate contains” has been deleted and has been replaced with the phrase “the particles are”.

On Page 5 of the Specification, in the third paragraph (Lines 10-15), the phrase “end product, whether pharmaceutical, nutritional, herbicidal, pesticidal or whatever.” has been deleted and has been replaced with “end product, such as a pharmaceutical product, a nutritional product, an herbicidal product, or a pesticidal product.”

On Page 26 of the Specification, in Lines 15-20, the phrase “pressure vessel as the particle formation vessel” has been deleted and has been replaced with “pressure vessel (available from Keystone Scientific, Inc., located in Bellefonte, PA) as the particle formation vessel”

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Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL HARTLEY
PRIMARY EXAMINER